JAN 12 2005

K043009

Attachment E

510(k) Summary of 510(k) Information

Summary of 510(k) Information

Company Name:	Jordan NeuroScience, Inc. 399 E. Highland Ave., Suite 316 San Bernardino CA 92404
Contact: Phone: Fax:	Anne Perry 909 881-2694 909 882-2891
Summary Date:	October 22, 2004
Trade Names:	BraiNet Kit (BraiNet® and BrainDisc™)
Common Name:	Electrode Cap & Subdermal EEG Needle electrodes and Cutaneous EEG electrodes
Classification Name:	21 CFR 882.1320; Product Code: GXY

Predicate Device:

510(k) Number:	K780045
Manufacture:	Electro-Cap International
Trade Name:	Electro-Cap, Infa-Cap

1.0 Description of Device

The BraiNet® Kit components are used by medical professionals and paraprofessionals to simplify placement of electroencephalograph (EEG) electrodes on the scalp. The electrodes connect to medical equipment in support of brain electrophysiology recording.

The BraiNet® Kit is provided to the user non-sterile, with the exception of the subdermal EEG needle electrodes which are provided sterile and prepackaged. The BraiNet® Kit & individual components is a single patient use, disposable device.

2.0 Intended Use

The intended use of the BraiNet® is the same as the predicate Eletro-Cap, Infa-Cap. The BraiNet® template is placed on the scalp to support electroencephalograph (EEG) electrode placement.

The intended use of the BrainDisc™ cutaneous electrode is the same as the predicate AMBU Disposable Cup Electrode. The BrainDisc™ is placed on the scalp to support electroencephalograph (EEG) recording.

3.0 Technological

The BraiNet® is made from commercial grade elastic and Velcro materials common to the garment industry.

The BrainDisc™ is made from medium grade polycarbonate with silver/silver-chloride center with attached insulated copper lead wire.

4.0 Conclusions

The intended use and technology of the BraiNet® Kit and contents is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Ms. Anne Perry
CFO
Jordan NeuroScience, Inc.
399 E. Highland Avenue, Suite 316
San Bernardino, California 92404

Re: K043009
Trade/Device Name: BraiNet® Kit
Regulation Number: 21 CFR 882.1320, 21 CFR 882.1350
Regulation Name: Cutaneous electrode; Needle electrode
Regulatory Class: II
Product Code: GXY and GXZ
Dated: October 22, 2004
Received: November 1, 2004

Dear Ms. Perry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Attachment A

Indications for Use Form

510(k) Number (if known): K043009 ~~3004622056 (Specification Developer)~~

Device Name: BraiNet® Kit

Indications For Use:

The BraiNet® Kit contents are placed on the scalp to support electroencephalograph (EEG) electrode placement.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043009

Prescription Use X OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional format 1-2-96)